

a generally cone-shaped head having a wide end, a narrow end, and at least two cutting edges defined by one or more generally planar surfaces wherein the cutting edges come together to form a pointed tip at the narrow end; and

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a collar member coupled to the head to secure the bone anchor in the bone.

REMARKS

Claims 10-13, 15, and 16 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,527,342 to Pietrzak et al. (hereinafter "Pietrzak") in view of U.S. Patent No. 5,792,142 to Galitzer (hereinafter "Galitzer").

Applicants hereby amend claim 10 to further define the subject matter of Applicants' invention. No new matter has been entered thereby. Support for the claim amendments can be found at least at page 3, lines 5-7 and 17, page 4, lines 4-7, page 6, lines 7-11, and page 6, line 28, to page 7, line 2.

Claims 10-13, 15, and 16 are currently pending and presented for reconsideration. In view of the above amendments and following remarks, reconsideration and withdrawal of all grounds of rejection are respectfully requested.

1. Claims 10-13, 15, and 16 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Pietrzak in view of Galitzer. Applicants respectfully traverse the rejection as applied to the claims, as amended.

Briefly, Pietrzak describes a bone anchor and an apparatus and method for implanting the anchor. The anchor comprises a cone-shaped head (col. 4, lines 56-60, and FIGS. 1-2)

coupled to a collar that can rotate with respect to the head (col. 5, line 66, to col. 6, line 1, and FIGS. 1 and 5-8).

Galitzer describes a cutting tip positioned on a threaded member that can be used to anchor a suture to bone (col. 3, lines 31-57, and FIGS. 1-3). Specifically, the cutting tip is carved out of one or more threads (col. 3, lines 58-60) and comprises a plurality of curved facets (col. 3, lines 44-45, col. 4, lines 54-62, col. 5, line 66, to col. 6, line 1, and FIGS. 1-3).

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. MPEP § 706.02(j) (citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)).

A *prima facie* case of obviousness has not been established with respect to claims 10-13, 15, and 16, as amended, for at least two reasons. First, neither Pietrzak nor Galitzer, alone or in proper combination, teaches or suggests all the limitations of independent claim 10, as amended. Second, the cited references provide no motivation to combine their teachings, and the Office Action fails to state with specificity any motivation to combine the cited references.

Applicants' amended claim 10 recites, in part, "a bone anchor . . . comprising: a generally cone-shaped head having a wide end, a narrow end, and **at least two cutting edges defined by one or more generally planar surfaces . . .**" In contrast, neither Pietrzak nor Galitzer teaches or suggests **cutting edges defined by one or more generally planar surfaces**. Specifically, Galitzer teaches an irregularly-shaped tip carved out of a threaded element which is inserted into a bone by a rotational force. The surfaces of the Galitzer tip are concave curved facets, not **generally planar surfaces**. In fact, the preferred method for forming the cutting tip according to Galitzer could not create a **generally planar surface**, because the milling tool itself is cylindrical (col. 4, lines 7-31, and FIG. 2). Thus, Galitzer does not teach or suggest a cone-shaped head with **cutting edges defined by one or more generally planar surfaces**. In addition, Pietrzak describes a conical bone anchor, but it does not teach or suggest **cutting edges or generally planar surfaces**. Accordingly, neither Pietrzak nor Galitzer, alone or in proper combination, teach or suggest all the limitations of amended claim 10 or claims 11-13, 15, and 16, which depend therefrom.

Furthermore, there is no motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine Pietrzak and Galitzer. According to MPEP § 2143.01, "[o]bviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art." MPEP § 2142. Furthermore, "[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art

suggests the desirability of the combination.” *Id.* (citing *In re Mills*, 916 F.2d 680, 16 USPQ 1430 (Fed. Cir. 1990)).

The bone anchor described by Galitzer contains a cutting tip positioned on a threaded member. Since the purpose of the threads is to secure the anchor within the bone, Galitzer does not suggest the need for a collar member to accomplish the same purpose. In addition, according to the MPEP, “[I]f a proposed modification or combination would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.” MPEP § 2143.02 (citing *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)). In this case, if a collar member similar to that described in Pietrzak were added to the Galitzer bone anchor, the collar would cover the anchor’s threads and render the threads useless for their intended purpose of securing the anchor in the bone. Thus, Galitzer does not suggest the combination with Pietrzak.

In addition, the knowledge generally available to one of ordinary skill in the art also fails to provide any motivation to combine Pietrzak and Galitzer, because the mechanism by which each bone anchor is implanted is completely different. The threaded bone anchor described by Galitzer must be screwed into a bone using a tool that can impart a rotational force to the anchor. In contrast, the bone anchor described by Pietrzak is driven directly into the bone using a forward linear force. Because of these different modes of implantation, the Pietrzak anchor could not be used according to the method described by Galitzer, and vice versa. Thus, one of ordinary skill in the art would not look to the teachings of Galitzer to modify the Pietrzak bone anchor.

Further, as stated in MPEP § 2142, “[t]he examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness.” As further stated in that section, “[w]hen the motivation to combine the teachings of the references is not immediately apparent, it is the duty of the examiner to explain why the combination of the teachings is proper.” *Ex parte Skinner*, 2 USPQ2d 1788 (Bd. Pat. App. & Inter. 1986). In particular, “the Board must identify specifically the principle, known to one of ordinary skill, that suggests the claimed combination.” *In Re Sang Su Lee*, 277 F.3d 1338, 1343 (Fed. Cir. 2002) (quoting *In Re Rouffet*, 149 F.3d 1350, 1359, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998)) (emphasis added). “The examiner can satisfy the burden of showing obviousness of the combination ‘only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references.’” *In Re Sang Su Lee*, 277 F.3d at 1343 (quoting *In Re Fritch*, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992)).

The Applicants respectfully submit that the combination proposed in the Office Action is without basis, because the Office Action does not provide with specificity any facts or arguments to show that the nature of the problem or the knowledge of one of ordinary skill in the art would suggest the combination of Pietrzak with Galitzer (and further with any other reference of record).

For these reasons, Applicants respectfully submit that independent claim 10 is allowable over Pietrzak in view of Galitzer. Because claims 11-13, 15, and 16 depend directly from independent claim 10, Applicants respectfully submit that these claims are allowable as

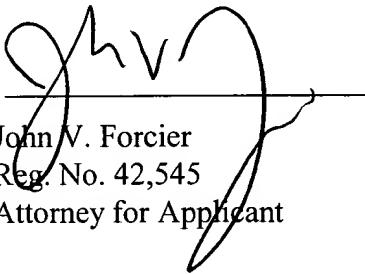
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well. Applicants respectfully request reconsideration and withdrawal of the rejection of claims 10-13, 15, and 16 under 35 U.S.C. § 103(a) as being unpatentable over Pietrzak in view of Galitzer.

CONCLUSION

Applicants respectfully request entry of this response and allowance of claims 10-13, 15, and 16 in due course. The Examiner is invited to contact Applicants' undersigned representative by telephone at the number listed below to discuss any outstanding issues.

Respectfully submitted,


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MARKED UP VERSION OF CLAIMS SHOWING AMENDMENTS

10. (Twice Amended) A bone anchor for use with a bone anchor implantation device comprising:

a generally cone-shaped head having a wide end, a narrow end, and at least two cutting edges defined by one or more generally planar surfaces wherein thesaid cutting edges come together to form a pointed tip at the narrow end ~~and the cutting edges of the head are defined by at least one curved surface~~; and

a collar member coupled to the head to secure the bone anchor in the bone.